MARK BRNOVICH
ATTORNEY GENERAL
(FIRM STATE BAR NO. 14000)

JEFFREY L. SPARKS (STATE BAR NO. 027536)
GINGER JARVIS (STATE BAR NO. 014887)
JASON EASTERDAY (STATE BAR NO. 023191)
ASSISTANT ATTORNEYS GENERAL

CAPITAL LITIGATION SECTION
2005 N. CENTRAL AVENUE
PHOENIX, ARIZONA 85004
TELEPHONE: (602) 542-4686
CLDOCKET@AZAG.GOV
ATTORNEYS FOR DEFENDANTS

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Clarence Wayne Dixon,
Plaintiff,

-v-

Arizona Department of Corrections, Rehabilitation & Reentry, et al.,
Defendants.

CV 22–00743–PHX–DJH (JFM)

NOTICE OF BEYOND USE DATE

Pursuant to this Court's Order of May 6, 2022 (Dkt. # 12), Defendants hereby provide notice that the Beyond Use Date for the compounded pentobarbital the State intends to use to execute Plaintiff next Wednesday, May 11, 2022, is **August 25, 2022**.

The Beyond Use Date of August 25, 2022, is supported by the attached affidavit from the pharmacist that prepared the pentobarbital solution to be used in Plaintiff's execution (Exhibit 1 ¶¶8-9). Defendants are providing the attached affidavit in compliance with the Court's 5/6/2022 Order and in express reliance on Plaintiff's 5/6/2022 representation that "the information requested by Plaintiff does not in any way threaten the confidentiality of the identity of 'executioners and other persons who participate or perform ancillary functions in an execution[.]'"

Dkt. 11 at 2 n.1 (quoting A.R.S. § 13–757(C)); *see also* A.R.S. § 13–757(C) ("The identity of executioners and other persons who participate or perform ancillary functions in an execution and any information contained in records that would identify those persons is confidential and is not subject to disclosure pursuant to title 39, chapter 1, article 2.").

Defendants also do not concede that any of Plaintiff's claims for relief require such disclosure in this or any other case, that any applicable burden of production or proof has shifted from Plaintiff to Defendants in this or any other case, and reiterate that Defendants do not in any way waive confidentiality of the affiant's identity under all applicable law, including A.R.S. § 13–757(C).

Respectfully submitted this 6th day of May, 2022.

Mark Brnovich
Attorney General

s/ Jeffrey Sparks
Chief Counsel

Ginger Jarvis
Jason Easterday
Assistant Attorneys General
Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2022, I electronically transmitted the attached document to the Clerk's Office using the ECF System for filing and served the attached document using ECF on the following registered participants of the ECF System:

Jennifer M. Moreno
Therese M. Day
Amanda C. Bass
Jennifer_moreno@fd.org
Therese_day@fd.org
Amanda_bass@fd.org

Attorneys for Plaintiff

s/ Jeffrey Sparks

SA49QAGW0EGKVK

EXHIBIT 1

I, [redacted] hereby declare as follows:

1. I am over 18 years of age and would testify to the following based on my first-hand knowledge.
2. I am a licensed pharmacist in the State of Arizona.
3. As a licensed pharmacist in the State of Arizona, I am aware of and follow the guidelines and requirements found in the United States Pharmacopeia.
4. I have prior experience in properly preparing compounded sterile preparations.
5. I prepared a sodium pentobarbital solution using my training and experience as a licensed pharmacist.
6. I had the prepared sodium pentobarbital solution provided to a FDA registered laboratory for stability testing in order to establish the solution's Beyond Use Date. (See Attachments 1-3).
7. These test results establish that the sodium pentobarbital solution has a Beyond Use Date of 180 days from the date of initial testing. (See Attachment 3).
8. On February 26, 2022, I prepared a sodium pentobarbital solution from the same sodium pentobarbital powder that was used for the stability study.
9. Based on the stability study test results, the Beyond Use Date of the solution I prepared on February 26, 2022 is August 25, 2022.

DATED this 5th day of May, 2022.

[redacted]

ATTACHMENT 1

[redacted]

Certificate of Analysis

CLIENT : [redacted]
DESCRIPTION : Stability - Pentobarbital Sodium 50 mg/mL
[redacted]
FORMULATION ID : [redacted]

DATE RECEIVED : 09/24/2021
STORAGE : 25°C & 60%RH

Test	Method	Specifications	Results	Date Tested
Assay - Pentobarbital Sodium	HPLC / AMIN-2089	92.0% - 108.0%	98.5% (49.2302mg / 1mL)	12/28/2021

Notes

Assay: The referenced method (AMIN-2089) used for this analysis is validated for the specific product being tested under non-cGMP conditions at client's request.

Time = Day 90 of testing at pre-defined timepoints.

[redacted]

01/04/2022

Date

[redacted]

Certificate of Analysis

DESCRIPTION : Stability - Pentobarbital Sodium 50 mg/mL

DATE RECEIVED : 09/24/2021
STORAGE : 25°C & 60%RH

Test	Method	Specifications	Results	Date Tested
Assay - Pentobarbital Sodium	HPLC / AMIN-2089	92.0% - 108.0%	98.1% (49.0310mg / 1mL)	01/27/2022

Notes

Assay: The referenced method (AMIN used for this analysis is validated for the specific product being tested under non-cGMP conditions at client's request.

Time = Day 120 of testing at pre-defined timepoints.

02/03/2022

Date

Certificate of Analysis

DESCRIPTION : Stability - Pentobarbital Sodium 50 mg/mL

DATE RECEIVED : 09/24/2021
STORAGE : 25°C & 60%RH

Test	Method	Specifications	Results	Date Tested
Assay - Pentobarbital Sodium	HPLC / AMIN-2089	92.0% - 108.0%	98.1% (49.0497mg / 1mL)	03/02/2022

Notes

Time = Day 150 of testing at pre-defined timepoints.

Assay: The referenced method (AMIN) used for this analysis is validated for the specific product being tested under non-cGMP conditions at client's request.

03/08/2022

Date

ATTACHMENT 2

[redacted]

Certificate of Analysis

[redacted]

DESCRIPTION : Stability - Pentobarbital Sodium 50 mg/mL

[redacted]

DATE RECEIVED : 09/24/2021
STORAGE : 25°C & 60%RH

Test	Method	Specifications	Results	Date Tested
Endotoxin	USP <85>	NMT 0.7 EU / mg	<0.2 EU / mg	03/24/2022
Sterility - (PRELIMINARY)	USP <71>	Sterile	No Growth at 5 Days	03/23/2022

Notes

Time = Day 180 of testing at pre-defined timepoints.

Sterility: The citation to USP <71> is conditioned on the accuracy of our customer's verification that the sampling program complies with the provisions of USP <71>.

[redacted]

03/28/2022

Date

[redacted]

[redacted]

Certificate of Analysis

[redacted]

DESCRIPTION : Stability - Pentobarbital Sodium 50 mg/mL

[redacted]

DATE RECEIVED : 09/24/2021
STORAGE : 25°C & 60%RH

Test	Method	Specifications	Results	Date Tested
pH	USP <791>	Report Value	10.6	03/24/2022
Assay - Pentobarbital Sodium	[redacted]	92.0% - 108.0%	100.3% (50.1515mg / 1mL)	03/28/2022

Notes

Assay: The referenced method [redacted] used for this analysis is validated for the specific product being tested under non-cGMP conditions at client's request.

Time = Day 180 of testing at pre-defined timepoints.

[redacted]

04/04/2022

Date

[redacted]

[redacted]

Certificate of Analysis

[redacted]

DESCRIPTION : Stability - Pentobarbital Sodium 50 mg/mL

[redacted]

DATE RECEIVED : 09/24/2021
STORAGE : 25°C & 60%RH

Test	Method	Specifications	Results	Date Tested
Sterility - (FINAL)	USP <71>	Sterile	Sterile	03/23/2022

Notes

Time = Day 180 of testing at pre-defined timepoints.

Sterility: The citation to USP <71> is conditioned on the accuracy of our customer's verification that the sampling program complies with the provisions of USP <71>.

[redacted]

04/06/2022

Date

[redacted]

[redacted]

Certificate of Analysis

[redacted]

DESCRIPTION : Pentobarbital Sodium 50 mg/ml

[redacted]

DATE RECEIVED : 04/12/2022
STORAGE : 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Assay - Pentobarbital Sodium	HPLC	90.0% - 110.0%	98.2% (49.0968mg / 1mL)	04/13/2022

Notes

The potency method(s) used for testing passed system suitability requirements per [redacted] for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

[redacted]

04/13/2022
Date

[redacted]

ATTACHMENT 3

[redacted]

STABILITY STUDY SUMMARY REPORT: PENTOBARBITAL

[redacted]

PROJECT SUMMARY AND RESULTS

Sample Description	Stability-Pentobarbital Sodium 50 mg/mL		
Concentration	50 mg/mL, Pentobarbital Sodium		
Formulation ID	4015	Dosage Form	Parenteral (IV)
Storage Condition	25°C ± 2°C/ 60%RH	Lot Number	39702
Container Description	30 mL amber vial w/ 20 mL fill		

Attribute	Methods	Specification (Description)	Initial (T0) ARL# 785881	T90 D ARL# 786008	T120 D ARL# 786023	T150 D ARL# 818437	T180 D ARL# 786025
pH	USP <791>	Report Value	NT	NT	NT	NT	10.6
Sterility	USP <71>	Sterile	Sterile	Sterile	NT	NT	Sterile
Endotoxin	USP <85>	NMT 0.7 EU/mg	<0.2 EU/mg	<0.2 EU/mg	NT	NT	<0.2 EU/mg
Pentobarbital Sodium Assay	AMIN-2089	% of Label (92.0-108.0%)	96.4%	98.5%	98.1%	98.1%	100.3%
Assay Date Tested	-	-	09/29/2021	12/28/2021	01/27/2022	03/02/2022	03/28/2022

CONCLUSION

Physical and chemical data of Pentobarbital Sodium has demonstrated that Pentobarbital Sodium in the present formula and packaging met client provided specifications through 180 days in ambient storage conditions.

[redacted]

[redacted]

[redacted]